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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,580	04/24/2001	Andrea Califano	YOR920000687US2	5406
48062 7590 02/26/2009 RYAN, MASON & LEWIS, LLP 1300 POST ROAD SUITE 205 FAIRFIELD, CT 06824			EXAMINER CLOW, LORI A	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 02/26/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/841,580	Applicant(s) CALIFANO ET AL.	
	Examiner Lori A. Clow	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 17-19, 23-25 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-19 is/are allowed.
- 6) ☒ Claim(s) 1-3, 23-25, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

Applicants' response, filed 2 January 2009, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-3, 17-19, 23-25, and 29 are currently pending and under exam herein. Claims 4-16, 20-22, and 26-28 have been cancelled.

Claim Rejections - 35 USC § 101-Non-statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 23-25, and 29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3 are drawn to a computer-implemented method for characterizing gene expression comprising executing, via a computer, the steps of determining gene expression, transforming data, determining gene expression patterns based on transformed data, generating a model, characterizing gene expression of a sample and outputting the characterization.

As stated in MPEP 2106, section IV if the claims are found to cover a judicial exception then the claims will be evaluated for providing a practical application of the judicial exception (*i.e.*, Law of Nature, Natural Phenomenon, or an Abstract Idea). This is in line with the recent

Art Unit: 1631

decision in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In the instant case, the claims are drawn to an abstract idea and therefore must be evaluated further for providing a practical application of the judicial exception. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely provide steps of *in silico* information manipulation. Therefore, none of said steps result in a physical transformation of matter such that the whole of the claim is statutory.

As such, the claims must be further evaluated for providing the practical application. One way to do this is for the claim to produce a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case the steps of "outputting said characterization to a user" **does** provide a tangible result that is useful to one skilled in the art and thus provides a practical application.

However, in addition to the facts set forth above that state that a claim must provide a practical application, the claim **must also meet** the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008)). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept **may have a practical application**, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on,

Art Unit: 1631

transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) the test for a method claim is whether the claimed method is (1) tied to a **particular** machine or apparatus or (2) transforms a particular article to a different state or thing.

In the instant case, the method claims are not so tied to another statutory class of invention because the **method** steps that are critical to the invention are "not tied to any **particular apparatus or machine**" and therefore do not meet the machine-or-transformation test as set forth in *In re Bilski* 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008).

Applicant states that, "as amended, independent claim 1 recites a tie to a particular machine or apparatus, namely, a computer".

This is not persuasive, as the recitation of a "computer-implemented method" and the recitation of "executing via a computer" in the preamble of the instant claims constitutes no more than a filed of use limitation that is not sufficient to render the claim patent-eligible. The "machine" recited in the instant claims does not impose meaningful limits on the scope of the method claims because the recited "computer" is not specific to each of the said method steps and the computer could be any such computer.

In addition to the above analysis regarding the said method claims, it is noted that claims 23-25 recite "an article of manufacture comprising a computer readable medium". The computer-readable medium of the instant claims reads on carrier waves, which read on transitory propagating signals which are not proper patentable subject matter because they do not fit within any of the four statutory categories of invention (*In re Nuijten*, Federal. Circuit, 2006). The

Art Unit: 1631

specification at page 10, a lines 8-15 indicate that a computer readable medium encompasses volatile and non-volatile data (floppy disks, hard drives, compact disks, memory cards, network comprising fiber optics, the world-wide web, cables, or a wireless channel using time-division multiple access, code-division multiple access, or other radio-frequency channel).

It is noted that claims 17-19 are not rejected under this statute, as the system provides a practical application of the judicial exception by providing an output of said characterization to a user.

Conclusion

The outstanding rejections under 35 USC 103(a) are hereby withdrawn in view of the claim amendments.

Claims 17-19 are allowable, as the prior art does not teach or fairly suggest a system for determining gene expression signals for a gene whereby control data is transformed by transforming a probability density distribution and a model is generated for the probability density function whereby the model is used to characterize gene expression of an unknown sample.

Claims 1-3, 23-25 and 29 remain rejected.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

February 26, 2009

/Lori A. Clow/

Primary Examiner, Art Unit 1631